

## STATUS OF THE CLAIMS

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Claims 1 and 2 are pending in the application.

Claims 1 and 2 were rejected under 35 USC§102(b) as being anticipated by Karow et al (WO 99/55404).

Claims 1 and 2 were rejected under 35 USC§102(b) as being anticipated by Brennan '852.

After entry of this Amendment B, Claims 1 and 2 remain pending in the application.

Summary of the Invention

An airborne contaminant indicating device adapted for attachment to a person's nose for indicating the presence of a microbial contaminant entrained in an air stream passing through the nose. In a particularly preferred embodiment, the device is a clip with a proximal "UU" shaped dilating portion adapted to be inserted within the nostrils; the "U's" being connected to one another medially by an elastically deformable extension portion, the extension portion being two straight parallel strips, one end of the strips being integral with the dilating portion and the opposing end of the strip integral with an arcuate septum attachment portion. The septum attachment portion spaces the distal ends of the strips of the extension portion so that the strips straddle and gently squeeze the nasal septum. The device has a contaminant-interactive coated surface in contact with a portion of the air passing through the nose. The design of the embodiment provides maximum air flow through the nostrils. The proximal, dilating portion of the device consists of two "U"

shaped strips, each strip being affixed to a proximal open end of the "U" shaped extension portion and at right angles to the plane of the extension portion. The dilating portion presents a smooth outer tissue-contacting surface which urges the inner surface of the walls of the nostrils forcing them outwardly. A portion of the surface in opposition to the tissue-contacting surface includes a microbial contaminant interactive coating that is adapted to immobilize microbial contaminants in the air.

#### The Rejection Under 35USC§102

Claims 1 and 2 were rejected under 35USC§102 as being anticipated by Karow et al '172, U.S. Patent 6,626,172 being an English language equivalent to international patent document WO 99/55404. Briefly, Karow discloses a device for insertion into the human nose, characterised by having at least one elastically deformable plate-like base element with an inner (mucosal-contacting) side and an outer (airstream-contacting) side and with a substantially rectangular shape, said element being substantially flat or slightly arched in its unstressed condition. Karow further teaches that the device is operable for the administration of pharmaceutical or diagnostic agents and for improving nasal breathing. The structural features of the embodiment of the device illustrated in Figures 7 and 8 are similar to the structural features of the present invention but differ in an important respect: the '172 patent does not teach or otherwise suggest the incorporation of a coating on the outer (airstream-contacting) side operable for immobilizing microorganisms entrained in the airstream. The "diffusion layer" or "matrix" 5 in Figure 5 of '172 is: (a) on the inner mucosal-contacting surface of the device and is adapted for dispensing pharmacologically active agents for transmucosal delivery. The examiner is in error when he states (page 3,

line 3 of the Office Action) that "... the inner surface (10) is in contact with the flow of respiratory air". It is the outer side (11) that is in contact with respiratory air. In column 6, lines 17-34, Karow et al. disclose placing recesses on the outer side (11) of the device in which cellulose sponges may be placed for the purpose of presenting allergens or for releasing volatile oils for inhalation. There is no suggestion of providing a microorganism-immobilizing coating such as, for example, gel-coated bristles, on the outer side of the device. A sponge won't get the job done.

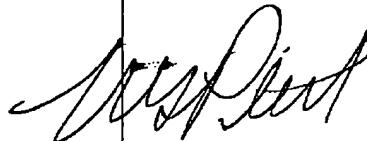
The present invention, on the other hand, teaches a nasal device operable for the immobilization of microbes, particularly pathogenic organisms entrained in the airstream within the nasal airway. Karow teaches the application of pharmaceutical or diagnostic agents to either the inside or the outside surface of the nasal device. Karow makes no mention of monitoring the level of exposure to environmental pathogens as described in this disclosure.

Claims 1 and 2 were rejected under 35USC§102 as being anticipated by Brennan '852 (Brennan is also the present inventor). The structure described in applicant's earlier patent is identical to that described in the instant application except that it does not disclose a coating on the outer airstream-contacting surface that is adapted to immobilize a microorganism. As stated earlier, in order for a patent to qualify as a reference supporting a §102 (b) rejection, it must disclose each and every limitation of the rejected claim. It is settled that even only slight differences between the compared inventions prevent a rejection based on lack of novelty under §102. In view of the differences between the elements of the present invention and those of the prior art, particularly a surface that immobilizes microbes in an airstream, it is requested that this rejection be withdrawn. In

anticipation of the obvious issues regarding double patenting, a terminal disclaimer is included with this response.

Entry of this amendment, reconsideration, favorable action and early allowance and publication of this application are respectfully requested. If there are any minor matters remaining, it is respectfully requested that the Examiner contact the undersigned by phone so that possible minor changes may be discussed in order to expedite the prosecution of this case.

Respectfully,



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